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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/940,419 | 08/29/2001 | Timothy Bateman | 0100/0134 | 5102 |

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EXAMINER

RADEMACHER, MARK A

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
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3761

DATE MAILED: 06/24/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/940,419

Applicant(s)

BATEMAN ET AL.

Examiner

Mark Rademacher

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 7-9 and 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 6 and 10-12 is/are rejected.
- 7) ☐ Claim(s) 4 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3, 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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1. Claims 7-9 and 13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim.

Election was made **without** traverse in Paper No. 6.

Priority

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-3 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by US patent no. 4,050,457 to *Davidson*.
5. *Davidson* discloses ventilation device in the form of a face shield used for mouth-to-mouth resuscitation. The device comprises a shield member (20) that extends across the nose and mouth of the patient. The shield includes an opening (21) in the region of the mouth. The shield also includes an adhesive layer (23) that seals around the mouth and nose of the patient so that the nose is blocked and the mouth opens through the opening. A tubular fitting in the form of lip flap construction (22) is formed in the shield. See, e.g., FIG 4 and column 2, lines 51-64.
6. The shield is constructed of a one-piece sheet of thin flexible material. Column 1, lines 53-54.

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7. Cheek pads are formed by the portions of the shield that extend from the nose and mouth to cover the cheeks of the patient. See, e.g., FIG 1.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-3 and 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over US patent no. 5511453 to *Shirley* in view of US patent no. 4050457 to *Davidson*.

10. *Shirley* discloses a disposable resuscitation device including a shield that a flexible sheet (12) that is adapted to seal around the nose and mouth and block the nose. A body (10) includes a tube that provides an opening in the sheet. The tube extends within the patient's mouth and at its other end projects externally. See, e.g., FIGS 7 and 8 and the accompanying discussion. The sheet may include laterally extending cheek pads. See, e.g., FIG 6.

11. *Shirley* does not expressly disclose the use of adhesive on the flexible sheet. However, the use of adhesive was well known at the time of invention. For example, US patent no. 4050457 to *Davidson* discloses a mouth-to-mouth shield that comprises a flexible sheet with an adhesive coating for securing the shield to the face of a patient. See column 2, lines 51-64.

12. Accordingly, at the time of invention, it would have been obvious to one with ordinary skill in the art to add an adhesive layer as taught by *Davidson* to the sheet of *Shirley* in order to secure the body to the face of a patient.

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13. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over US patent no. 4,050,457 to *Davidson* in view of US patent no. 5,666,950 to *Smith*.

14. *Davidson* discloses all of the features recited in claim 6 without expressly disclosing a hydrocolloid type adhesive used in adhesive layer (23).

15. However, the use of hydrocolloid adhesives for items that contact a patient was well known at the time of invention. For example, *Smith* discloses a filter device that seals around a stoma in a patient. The seal is provided by an adhesive that is preferably a hydrocolloid composition, which reduces skin maceration. See, e.g., column 5, lines 12-18.

16. Accordingly, at the time of invention it would have been obvious to one with ordinary skill in the art to use a hydrocolloid adhesive for the adhesive layer (23) of the *Davidson* shield in order to reduce skin maceration.

17. Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over published US application no. US 2002/0092526 A1 *Bertoch et al* in view of US patent no. 4,050,457 to *Davidson*.

18. *Bertoch et al* disclose a securing device for an endotracheal tube that includes a flexible shield (10) that is configured to extend across the mouth and nose of the patient. The shield includes a tubular fitting in the form of a clamp (20) that secures and receives a removable endotracheal tube (40) for ventilation via the mouth.

19. *Bertoch et al* further disclose that the shield is preferably made of a transparent material. See paragraph 45.

20. *Bertoch et al* do not expressly disclose that the shield is an adhesive shield. However, the use of adhesive to secure respiratory devices to the face of a patient was well known at the time

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of invention. For example, *Davidson* discloses the use of adhesive (23) to secure a face shield to a patient. See, e.g., column 2, lines 51-64.

21. At the time of invention it would have been obvious to one with ordinary skill in the art to add adhesive to the shield disclosed by *Bertoch et al* in order to secure the shield in position on a patient's face.

Allowable Subject Matter

22. Claim 4 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Additional Pertinent Prior Art

23. The following prior art is considered pertinent to applicant's disclosure: US patent no. 5,088,485 to *Schock*.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Rademacher whose telephone number is (703) 305-0842. The examiner can normally be reached on Monday through Friday, 9:30am - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on (703) 308-1957. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

MAR
June 12, 2003

Glenn
GLENN K. DAWSON
PRIMARY EXAMINER